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NIXON & VANDERHYE, PC			MACAULEY, SHERIDAN R	
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ARLINGTON, VA 22203			1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/574,854	WNUKOWSKI ET AL.
	Examiner	Art Unit
	Sheridan R. MacAuley	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 July 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) 7 and 19 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/6/2006.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claims 1-19 are pending.

Election/Restrictions

1. Applicant's election of species of compounds ("unstable compounds") in the reply filed on July 30, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is deemed to be proper and is therefore made FINAL.
2. The nonelected species are withdrawn from further consideration pursuant to 37 CFR 1.142(b), there being no allowable generic or linking claim.
3. Claims 1-19 are examined on the merits in this office action.

Claim Objections

4. Claims 7 and 19 are objected to because of the following informalities. It is recommended that the claims be amended as follows: In claim 7, the phrase "matrix is" should be changed to "matrix, which is", or some other appropriate phrase. In claim 19, it is recommended that the word "pharmaceutical" be changed to "pharmaceutically". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. The term "suitable" in claim 1 (in steps (a), (b) and (c)) is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, one skilled in the art might define "suitable" to mean 10 milliliters, one liter, or ten liters.
8. Claims 2-19 are also indefinite insofar as they depend from claim 1.
9. In claims 2 and 3, it is also unclear whether the positions at which the filters are disconnected and connected refer to actions that are carried out in step (b) of the method of claim 1, or whether applicant intends for these steps to be carried out at another point during the process.
10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation 0.05 to 400 liters per minute, and the claim also recites 20 to 100 liters per minute and 30 to 40 liters per minute, which are the narrower statements of the range/limitation. Also, claim 9 recites the broad recitation 1 to 50 liters per square meter per minute, and the claim also recites 1.5 to 20 liters per square meter per minute and 1.5 to 10 liters per square meter per minute, which are the narrower statements of the range/limitation.

11. In claim 10, the phrase "minus degrees C to" also renders the claim indefinite because applicant did not specify a value for the lower temperature in the range.

12. The term "unstable" in claim 12 is a relative term that renders the claim indefinite. The term "unstable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, almost any compound would be unstable at certain conditions. Since no condition has been specified to describe the conditions under which the claimed compound would be unstable, one of ordinary skill in the art would be unable to ascertain which unstable compounds are being claimed.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-5, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Corson et al. (US Pat. 3,551,203). Claim 1 recites a process for purification of a compound comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix, the treatment comprising: a) passing a suitable volume of a feed containing the compound over a first series of n connected filter units operating in series to obtain an effluent, wherein n is at least two, said filter units having been assigned a position number 1 to n in the series and position number 1 being the first supplied with the feed, b) disconnecting a filter unit from the first series of filter units at any position number between 1 to n-1 after passing the suitable volume of feed, and connecting a fresh filter unit at any position that has a higher number than the position number of the disconnected filter unit, resulting in a next series of filter units, c) passing a next suitable volume of feed containing the compound over the next series of filter units to obtain a next effluent, d) optionally combining the effluents obtained in a and c, and e) recovering the compound from the effluent. Claims 2-4 recite the method of claim 2 wherein the filter is disconnected at a position between 1 and n-1, specifically 1, and the fresh filter is connected at position n+1. Claim 5 recites that the treatment of claim 1 is done in batch, continuous, or semi-continuous mode. Claim 10 recites that

the process of claim 1 is operated at a temperature from a negative value to 40 degrees

C. Claim 12 recites that the compound of claim 1 is an unstable compound.

15. Corson teaches a process for purification of a compound (dextrose) comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix (a filter), the treatment comprising: passing feed containing the compound over a first series of connected filter units operating in series to obtain an effluent; disconnecting an upstream filter unit from the first series of filter units and connecting a downstream filter unit; passing a next volume of feed containing the compound over the filter unit; and recovering the compound (col. 8, lines 1-14, col. 9, lines 22-34). In the process of Corson, the first filter in the series is disconnected and the fresh filter which is connected is the last filter in the series (col. 9, lines 22-34). Corson teaches the use of 2 to 5 filters in series (col. 3, lines 49-50). The process of Corson may be operated in batch mode (col. 8, lines 1-14). The dextrose purified by Corson could be considered an unstable compound. Corson teaches that the method may be operated at room temperature, which would be between zero and 40 degrees C (col. 5, lines 41-42).

16. Therefore, Corson anticipates all of the limitations of the cited claims.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1-6 and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corson et al. (US Pat. 3,551,203) in view of Dalton (US 2,655,497). Claim 1 recites a process for purification of a compound comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix, the treatment comprising: a) passing a suitable volume of a feed containing the compound over a first series of n connected filter units operating in series to obtain an effluent, wherein n is at least two, said filter units having been assigned a position number 1 to n in the series and position number 1 being the first supplied with the feed, b)

disconnecting a filter unit from the first series of filter units at any position number between 1 to n-1 after passing the suitable volume of feed, and connecting a fresh filter unit at any position that has a higher number than the position number of the disconnected filter unit, resulting in a next series of filter units, c) passing a next suitable volume of feed containing the compound over the next series of filter units to obtain a next effluent, d) optionally combining the effluents obtained in a and c, and e) recovering the compound from the effluent. Claims 2-4 recite the method of claim 2 wherein the filter is disconnected at a position between 1 and n-1, specifically 1, and the fresh filter is connected at position n+1. Claim 5 recites that the treatment of claim 1 is done in batch, continuous, or semi-continuous mode. Claims 6 and 9 recite that the flow rate in the process of claim 1 is 0.05 to 400 L/min and that the residence time of the feed in a single filter unit is between 15 seconds and 60 minutes. Claim 10 recites that the process of claim 1 is operated at a temperature from a negative value to 40 degrees C. Claim 11 recites that the disconnected filter is regenerated in situ by rinsing with a solvent. Claims 12-14 and 18 recite that the compound of claim 1 is an unstable compound, particularly a secondary metabolite or a protein, specifically an antibiotic, vitamin, carotenoid or PUFA, specifically cluvulanic acid, streptomycin, chloramphenicol, tetracycline or beta-carotene. Claims 15-17 recite the process of claim 12 wherein the compound is obtained by fermentation using a microorganism, particularly a *Streptomyces* species, specifically *S. clavuligerus*, *S. griseus*, *S. venezuelae*, *S. jumonjinesis*, *S. katsurahamanus*, or *S. aureofaciens*. Claim 19 recites

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the process of claim 1 further comprising the step of converting the compound into a pharmaceutically acceptable salt or food grade product.

21. Corson teaches a process for purification of a compound (dextrose) comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix (a filter), the treatment comprising: passing feed containing the compound over a first series of connected filter units operating in series to obtain an effluent; disconnecting an upstream filter unit from the first series of filter units and connecting a downstream filter unit; passing a next volume of feed containing the compound over the filter unit; and recovering the compound (col. 8, lines 1-14, col. 9, lines 22-34). In the process of Corson, the first filter in the series is disconnected and the fresh filter which is connected is the last filter in the series (col. 9, lines 22-34). Corson teaches the use of 2 to 5 filters in series (col. 3, lines 49-50). The process of Corson may be operated in batch mode (col. 8, lines 1-14). Corson teaches that the flux is 5 to 40 gallons per hour per square feet of filter, which is equal to 3.4 to 27 liters per minute per square meters (col. 4, lines 56-65). The dextrose purified by Corson could be considered an unstable compound. Corson teaches that the method may be operated at room temperature, which would be between zero and 40 degrees C (col. 5, lines 41-42). Corson teaches that the filter may be regenerated using solvents (col. 5, lines 50-56).

22. Corson does not specifically teach that the process is carried out at the claimed flow rate or with the claimed residence time within a filter. Corson does not teach the regeneration of the disconnected filter in situ. Corson does not teach that the compound is a secondary metabolite or protein, specifically not those recited in the

claims, or that the compound is obtained by microbial fermentation, particularly not with the claimed *Streptomyces*. Corson does not specifically teach the conversion of the compound into a pharmaceutical or food grade product.

23. Dalton teaches a process for the purification of streptomycin from a solution resulting from the microbial fermentation of *Streptomyces griseus* (col. 1, lines 22-32, col. 5, example 1). Dalton teaches that the purification of streptomycin is effected by passing the solution through a filter comprising activated carbon (col. 1, lines 22-32).

24. At the time of the invention, a process for carrying out activated carbon filtration for the recovery of a compound using the claimed series of filters was known, as taught by Corson. It was also known at the time of the invention that streptomycin obtained by microbial fermentation could be purified using an activated carbon filter, as taught by Dalton. Although neither Corson or Dalton specifically disclose the downstream processing of the compounds into pharmaceutical or food grade products, one of ordinary skill in the art would recognize that both dextrose and streptomycin are desirable components of pharmaceutical or food products; one would thus be motivated to produce pharmaceutical or food grade products from the compounds purified by these methods. One of ordinary skill in the art would have been motivated to combine the teachings of Corson and Dalton because Dalton teaches that the use of activated carbon with a small mesh size can result in clogging of the filter (col. 2, lines 10-15). Corson teaches a method whereby filters may be taken out of operation and replaced by fresh filters. One of ordinary skill in the art would therefore have recognized that it would have been advantageous to use the filtration method of Corson to purify

streptomycin by the method of Dalton. Although Corson does not specifically teach the claimed flow rate or the claimed residence time, one of ordinary skill would recognize that the filter size could be selected by routine experimentation, and it would be likely that one would select a filter that resulted in a flow rate within the claimed range. For example, Corson teaches that the flux is 5 to 40 gallons per hour per square feet of filter; if a filter of one square foot were used with the method of Corson, the flow rate would be about 0.32 to 2.5 liters per minute. Likewise, the residence time either would have been within the claimed range if the flux taught by Corson was used, or it would have been a matter of routine experimentation to arrive at the claimed residence time. Further, the regeneration of the filter in situ would have been a matter of routine optimization in the method of Corson, who teaches that the filter may be regenerated by treatment with solvents; although Corson does not teach regeneration in situ, one would recognize that the use of a section of a filtration apparatus which has been closed to the rest of the system could have been used to treat a filter with a solvent. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings discussed above because the purification of streptomycin using activated carbon filtration was known to be effective, and Dalton teaches a method for filtration using activated carbon. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

25. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corson et al. (US Pat. 3,551,203) in view of Dalton (US 2,655,497), as applied to claims

1-6 and 9-19 above, and further in view of Kelly (US 5,980,612). Claim 1 recites a process for purification of a compound comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix, the treatment comprising: a) passing a suitable volume of a feed containing the compound over a first series of n connected filter units operating in series to obtain an effluent, wherein n is at least two, said filter units having been assigned a position number 1 to n in the series and position number 1 being the first supplied with the feed, b) disconnecting a filter unit from the first series of filter units at any position number between 1 to n-1 after passing the suitable volume of feed, and connecting a fresh filter unit at any position that has a higher number than the position number of the disconnected filter unit, resulting in a next series of filter units, c) passing a next suitable volume of feed containing the compound over the next series of filter units to obtain a next effluent, d) optionally combining the effluents obtained in a and c, and e) recovering the compound from the effluent. Claims 2-4 recite the method of claim 2 wherein the filter is disconnected at a position between 1 and n-1, specifically 1, and the fresh filter is connected at position n+1. Claim 5 recites that the treatment of claim 1 is done in batch, continuous, or semi-continuous mode. Claims 6, 8 and 9 recite that the flow rate in the process of claim 1 is 0.05 to 400 L/min, that the flux is 1 to 50 liters per meter squared per minute. Claim 7 recites that the activated carbon matrix of claim 1 is in the form of a membrane sheet. Claim 10 recites that the process of claim 1 is operated at a temperature from a negative value to 40 degrees C. Claim 11 recites that the disconnected filter is regenerated in situ by rinsing with a solvent. Claims 12-14 and 18 recite that the

compound of claim 1 is an unstable compound, particularly a secondary metabolite or a protein, specifically an antibiotic, vitamin, carotenoid or PUFA, specifically cluvulanic acid, streptomycin, chloramphenicol, tetracycline or beta-carotene. Claims 15-17 recite the process of claim 12 wherein the compound is obtained by fermentation using a microorganism, particularly a *Streptomyces* species, specifically *S. clavuligerus*, *S. griseus*, *S. venezuela*, *S. jumonjensis*, *S. katsurahamanus*, or *S. aureofaciens*. Claim 19 recites the process of claim 1 further comprising the step of converting the compound into a pharmaceutically acceptable salt or food grade product.

26. Corson teaches a process for purification of a compound (dextrose) comprising an activated carbon treatment using a filter unit containing activated carbon immobilized in a matrix (a filter), the treatment comprising: passing feed containing the compound over a first series of connected filter units operating in series to obtain an effluent; disconnecting an upstream filter unit from the first series of filter units and connecting a downstream filter unit; passing a next volume of feed containing the compound over the filter unit; and recovering the compound (col. 8, lines 1-14, col. 9, lines 22-34). In the process of Corson, the first filter in the series is disconnected and the fresh filter which is connected is the last filter in the series (col. 9, lines 22-34). Corson teaches the use of 2 to 5 filters in series (col. 3, lines 49-50). The process of Corson may be operated in batch mode (col. 8, lines 1-14). Corson teaches that the flux is 5 to 40 gallons per hour per square feet of filter, which is equal to 3.4 to 27 liters per minute per square meters (col. 4, lines 56-65). The dextrose purified by Corson could be considered an unstable compound. Corson teaches that the method may be operated at room temperature,

which would be between zero and 40 degrees C (col. 5, lines 41-42). Corson teaches that the filter may be regenerated using solvents (col. 5, lines 50-56).

27. Corson does not specifically teach that the process is carried out at the claimed flow rate or with the claimed residence time within a filter. Corson does not teach the regeneration of the disconnected filter in situ. Corson does not teach that the compound is a secondary metabolite or protein, specifically not those recited in the claims, or that the compound is obtained by microbial fermentation, particularly not with the claimed *Streptomyces*. Corson does not specifically teach the conversion of the compound into a pharmaceutical or food grade product.

28. Dalton teaches a process for the purification of streptomycin from a solution resulting from the microbial fermentation of *Streptomyces griseus* (col. 1, lines 22-32, col. 5, example 1). Dalton teaches that the purification of streptomycin is effected by passing the solution through a filter comprising activated carbon (col. 1, lines 22-32).

29. It would have been obvious to combine the teachings of Corson and Dalton at the time of the invention, as discussed above. Neither Corson nor Dalton, however, teach the use of immobilized activated carbon in the form of a membrane sheet.

30. Kelly teaches an activated carbon fiber sheet filter wherein the activated carbon is immobilized to the sheet, i.e. membrane (abstract). Kelly teaches that the sheet is suitable for the removal of compounds from a fluid stream (col. 1, lines 3-15).

31. At the time of the invention, a method for the purification of a compound comprising nearly all of the claimed elements was known, as taught by Corson and Dalton. A sheet containing immobilized activated carbon for the separation of

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compounds from fluids was also known, as taught by Kelly. One of ordinary skill in the art would have been motivated to combine these teachings by using the filter of Kelly in the claimed method because Kelly teaches that the immobilized carbon sheet is more effective than standard activated carbon filters because it enhances the surface area and allows for greater adsorption of the compounds to the filter (col. 1, lines 29-44, col. 3, lines 5-12). One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because the claimed invention is directed to the purification of a compound using a carbon filter, and Kelly teaches a carbon filter that is useful for such purification. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

32. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A Davis/
Primary Examiner, AU 1651